

Applicant(s) : Guangwen WEI
U.S. Serial No.: 10/650,365
Filed : August 28, 2003
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Restriction Requirement

The Examiner to whom this Application is assigned indicated that restriction to one of the following inventions is required under 35 U.S.C. § 121:

- 1: Claims 1-9, 11, and 23-24, drawn to a recombinant "super-compound" interferon and compositions comprising said "super-compound" interferon classified in class 530, subclass 350;
- 2: Claims 12-16, drawn to polynucleotides, vectors, host cells, and a method of making a recombinant "super-compound" interferon, classified in class 536, subclass 23.1 and classified in class 435, subclasses 325.30.1/69.1.
- 3: Claims 25 and 27-28, drawn to methods for preventing or treating viral diseases, said methods comprising administering a "super-compound" interferon, classified in class 424, subclass 85.4.
- 4: Claims 25 and 27-28, drawn to methods for preventing or treating tumors, said methods comprising administering a "super-compound" interferon, classified in class 424, subclass 85.4.

The Examiner stated that the inventions are distinct, each from the other because of the following reasons:

- A. Inventions of groups 1 (polypeptides) and 2 (polynucleotides) are distinct from one another because polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules than polypeptides, which are

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composed of amino acids; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The Examiner further stated that polypeptides can be made by another materially different process than from recombinant polynucleotide expression, such as chemical synthesis or isolation/purification from natural sources.

- B. Inventions 1 and 3/4 are related as product and process of use. In the instant case the product can be used in a materially different process, such as the production of antibodies.
- C. Inventions 2 and 3/4 are unrelated because the products of invention 2 are not used or otherwise involved in the methods of inventions 3 or 4.
- D. Inventions 3-4 are each unrelated to one another. In the instant case the different inventions are not disclosed as capable of use together. The Examiner further stated that inventions 3-4 are each directed towards different methods that have different modes of operation, different functions, different starting materials, different effects, and/or different outcome measures.
- E. Furthermore, searching the inventions together would impose a serious burden on the Examiner because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or separate search requirement based on particular aspects of the inventions.

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In response, Applicants respectfully traverse the above restriction requirement.

Under 35 U.S.C. 121, an application may properly be restricted to one of two or more claimed inventions only if said claimed inventions are either independent or distinct and are able to support separate patents. MPEP § 803. The term "independent" means that there is no disclosed relationship between the two or more subjects disclosed. In other words, they are unconnected in design, operation, or effect. MPEP § 802.1.

Burden

Additionally, the Examiner must make a *prima facie* showing that there is a serious burden on him/her, by appropriate explanation of separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. MPEP § 803.

Applicants maintain that the method of Invention 2 describes how to make the composition of Invention 1. Inventions 3 and 4 describe uses of the composition of Invention 1. A search utilizing key terms relating to interferons with high potency should reveal prior art relating to all of the following: a recombinant "super-compound" interferon (Group 1); a method of making said interferon (Group 2); and uses of said interferon (Groups 3 and 4). Therefore, all pending claims are connected by a single, searchable relationship. Accordingly, the Examiner would not be seriously burdened by searching and examining the claims of Groups I-IV in a single application.

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Election

In the event that the Examiner decides that the above arguments are not persuasive, Applicants elect Invention 1, with traverse, directed to claims 1-9, 11, and 23-24, drawn to a recombinant "super-compound" interferon and compositions comprising said "super-compound" interferon. In further response to page 6 of this Office Action, Applicants elect Interferon- α for further prosecution.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai Kit Chan

Albert Wai-Kit Chan
Registration No. 36,479
Attorney for Applicant(s)
Law Offices of
Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, New York 11357
Tel: (718) 357-8836
Fax: (718) 357-8615
E-mail: kitchanlaw@aol.com

I hereby certify that this paper is being facsimile transmitted to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Fax No.: (703) 872-9306
on the date shown below.
<u>Albert Wai-Kit Chan</u> <u>5/20/05</u>
Albert Wai-Kit Chan Date
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